REMARKS

Upon entry of the above amendments, claims 40-60 will be pending in the present application. Claims 45-48 are withdrawn from consideration.

I. Amendments

Applicant has amended claims 40, 43-44, and 49 and added new claims 53-60. Claim 40 has been amended so that the claim is directed to "[a] composition for treating inflammatory components of a hormonally-dependent cancer ..." The Examiner has already stated that there is support for this claim. (*See* Office Action dated 10/02/08, page 5.) Claims 43-44 and 49 have been amended to correct typographical errors. Support for new independent claim 53 can be found at ¶ [019]. Support for dependent claims 54-60 can be found throughout the specification. No new matter has been added by these amendments.

II. Title

Applicant has noticed that the title of the present application is incorrect on the Bibliographic Data Sheet (hereinafter the "Bib Sheet") entered on October 2, 2008 in the Image File Wrapper on the Patent Application Information Retrieval portal (hereinafter "PAIR") and also on the Application Data on PAIR. Applicant amended the title to the instant application in a Preliminary Amendment filed at the time the application was filed on March 30, 2004. The amended title is "Compositions for Treating Hormonally-Dependent Cancers." Applicant respectfully requests that this amendment be entered.

III. Priority

Applicant has amended the specification to include a priority statement that accurately reflects the chain of priority for the instant application. This priority information was included in Applicant's Preliminary Amendment filed at the time the present application was filed on March 30, 2004. Applicant has noticed that the Bib Sheet entered on PAIR on October 2, 2008 states that this application is "a DIV of 09/771,664." This appears to be a clerical error as the present application is a continuation-in-part application of PCT/US02/00476 which is a continuation-in-

part application of U.S. Application No. 09/771,***669***. The '669 application, now U.S. Patent No. 6,984,667, is a continuation-in-part application of U.S. Application No. 09/056,707, now U.S. Patent No. 6,689,748.

Based upon the above amendments and remarks, Applicant believes the priority claim of the instant application is now correct.

IV. Double Patenting Rejection

The Examiner rejected claims 40, 43, and 49-51 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent Nos. 6,635,625, 6,645,482, 6,624,148, 6,641,806, 6,984,667, and 7,115,278. (*See* Office Action, pages 2-3.) The Examiner also rejected claims 41-42, 44, and 52 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 6,635,625. (*See id.*)

The Examiner provisionally rejected claims 40, 43, and 49-51 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over co-pending U.S. Application No. 10/610,909. (*See id.* at page 4.)

Applicant is filing a terminal disclaimer for U.S. Patent Nos. 6,635,625, 6,645,482, 6,624,148, 6,641,806, 6,984,667, and 7,115,278 and U.S. Application No. 10/610,909 with this Response.

V. Claim Rejections – 35 U.S.C. § 112, 1st Paragraph

The Examiner rejected claims 40, 43, and 49-51 under 35 U.S.C. § 112, 1st paragraph, as allegedly lacking enablement for the treatment of cancer. The Examiner stated that "the specification … does not reasonably provide enablement for the treatment of the cancer." (Office Action, page 5.) Applicant has amended independent claim 40 to recite "[a] composition for treating inflammatory components of a hormonally-dependent cancer …" The Examiner has stated that specification is "enabling for treatment of inflammatory components of a hormonally-dependent cancer …" (*See id.*) Claims 43 and 49-51 depend from claim 40 and,

thus, are also directed to the treatment of inflammatory components of a hormonally-dependent cancer.

New claims 53-60 are directed to compositions for treating hormonally-dependent cancer that comprise, among other things, chemotherapeutic agents. Support for this composition can be found at ¶ [019] which states, in pertinent part, that the "compositions are used against the inflammatory components of hormonally-related cancers, … and when supplemented with chemotherapeutic agents are used against the cancer itself."

Based on the foregoing amendments and remarks, Applicant believes the pending claims comply with 35 U.S.C. § 112, 1st paragraph, and respectfully requests that the enablement rejection be withdrawn.

VI. Claim Rejections – 35 U.S.C. § 103(a)

The Examiner has rejected claims 40, 43, and 49-51 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Florio (WO 97/21434), in view of Singh et al. (U.S. Patent No. 5,858,371), Nobile et al. (U.S. Patent No. 4,265,823) (in light of Dr. Duke's phytochemical and ethnobotanical database), Widyarini et al., and High et al. (U.S. Publication No. 2002/0028779). Applicant respectfully traverses this rejection.

As discussed above, Applicant has amended the specification to include a priority statement that accurately reflects the chain of priority for the instant application. This application now correctly claims priority back to U.S. Patent No. 6,689,748, which has an effective filing date of April 8, 1998.

The Examiner cited Singh et al. for disclosing "that quercetin is known to have anti-inflammatory activity." (Office Action at page 7.) Singh issued January 12, 1999. The Examiner cited Widyarini et al. for teaching "that isoflavonoids, such as phenoxodiol (dehydroequol), and genistein, are potent anti-inflammatory agents." (*Id.*) Widyarini was

published in September 2001. The Examiner cited High et al. for teaching "that genistein is known to have anti-inflammatory activity." (*Id.*) High et al. was published on March 7, 2002.

The invention of the '748 patent relates to the "treatment of mast cell-induced diseases." (col. 1, lines 8-9.) The '748 patent disclosed that "[m]ast cells…play an important role in allergy and inflammation" and that "[m]ast cells…can secrete numerous…inflammatory mediators." (col. 1, lines 15-17, 25-26.) The '748 patent also disclosed that flavonoids inhibit mast cell secretion. (See col. 3, lines 48-49) The '748 patent described one aspect of its invention as a method consisting "of administering a proteoglycan combined with one or more synergistic adjuvants (such as those belonging to the class of flavonoids (such as myrisetin, quercetin, genisetin [*sic*] or kaempferol) …" (col. 4, lines 14-19.) Thus, a person of skill in the art would understand that the '748 patent described the use of flavonoids to inhibit mast cell secretion of inflammatory mediators that cause inflammation.

Therefore, because Singh, Widyarini, and High were issued or published after the '748 patent was filed, and because the '748 patent described the anti-inflammatory activity of flavonoids, and particularly of quercetin and genistein, Singh, Widyarini, and High cannot be used as part of an obviousness rejection under 35 U.S.C. § 103(a).

The Examiner has cited Florio for teaching an anti-inflammatory composition comprising chondroitin sulfate for symptomatic relief from arthritis. (*See* Office Action, page 7; Florio, abstract.) However, the Examiner has acknowledged that Florio "does not teach expressly the employment of quercetin, olive kernel extract, and isoflavonoids, such as genistein and phenoxodiol." (Office Action at page 7.) As discussed above, none of Singh, Widyarini, or High can be used as part of an obviousness rejection under 35 U.S.C. § 103(a) in light of the corrected priority claim. Thus, a person of ordinary skill in the art would have no reason to combine the arthritis-relieving composition of Florio with flavonoids or isoflavonoids.

Moreover, cancer inflammation is not the same as inflammation present in arthritis. A mast cell may secrete inflammatory anti-tumor molecules or inflammatory pro-tumor molecules.

Examples of the inflammatory anti-tumor molecules include tumor necrosis factor (TNF), interleukin-1, interleukin 4 and interleukin-6. By contrast, examples of inflammatory pro-tumor molecules include vascular endothelial growth factor (VEGF), heparin, histamine, platelet-derived growth factor (PDGF), nerve growth factor (NGF) and stem-cell factor (SCF). When the mast cell penetrates a tumor, for example, the mast cell does not release TNF, but secretes VEGF. The secretion of VEGF results in neovascularization (neoangiogenesis) and permits tumor nourishment. Therefore, the random selection of anti-inflammatory treatments, without more information, may result in nourishing a tumor, instead of treating a tumor. As such, the treatment of inflammation, by itself, does not clarify whether the treatment is directed at, for example, TNF or VEGF.

For the foregoing reasons, a person of ordinary skill in the art would have no reason to combine the arthritis-relieving nutritional supplements disclosed in Florio with flavonoids or isoflavonoids in order to treat cancer or the inflammatory components of cancer. As such, Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

Applicant believes the rejections maintained in the Office Action have been overcome and that the application is in condition for allowance. Applicant respectfully requests that a timely Notice of Allowance be issued.

The Director is hereby authorized to charge Deposit Account No. 08-0219, under Order No. 2003133.125US10, the fee of $405 for the Request for Continued Examination pursuant to 37 C.F.R. § 1.17(e).

Applicant believes no additional fees are due with this Request for Continued Examination and Response to Final Office Action. However, if such a fee is due, or a credit is owed, the Director is hereby authorized to make them to our Deposit Account No. 08-0219, under Order No. 2003133.00125US10.

The Examiner is encouraged to call the undersigned at the telephone number given below to move this application towards allowance.

Respectfully submitted,

Dated: December 9, 2008

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